K090871

BONE SUPPORT
injecting new strength

SEP - 4 2009

510(k) Summary

Submitter Information

Manufacturer	BONESUPPORT AB Scheelevägen 19 A Ideon Science Park SE-223 70 LUND, SWEDEN
Telephone	+ 46 46 286 53 70
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Contact person	Ann-Christine Provoost ann-christine.provoost@bonesupport.com + 46 46 286 53 22 (direct phone)
Date of preparation	9th of June, 2009

Trade name, Classification name, Class, Regulation

Trade Name	CERAMENT™|BONE VOID FILLER (A 0210-12)
Classification Name	Resorbable calcium salt bone void filler device
Class	CLASS II (Special Control)
Regulation Number	CFR 888.3045
Product Code	MQV

Predicate devices

510(k) number	Trade name	Manufacturer
K073316	CERAMENT™|BONE VOID FILLER (A 0210)	BONESUPPORT AB

Device description

CERAMENT™|BONE VOID FILLER is an injectable ceramic bone substitute material intended for bone voids/gaps. The material consists of a powder and a liquid component. The major constituents of the powder are calcium sulfate and hydroxyapatite. The liquid component contains iohexol as a radio-opacity enhancer. Mixing the components, with the combined mixing injection device, results in a viscous material suitable for injection into a bone void/gap. During resorption of the calcium sulfate dihydrate, the hydroxyapatite remains intact providing osteoconductive support for in-growth of new bone.

The ceramic bone substitute material is injected into the bone void/gap, under visual inspection or under radiographic monitoring, with the use of the accompanying injection devices.

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Intended use

CERAMENT™|BONE VOID FILLER is a ceramic bone void filler intended only for orthopedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. CERAMENT™|BONE VOID FILLER is indicated to be injected into bony voids or gaps in the skeletal system, i.e. extremities, pelvis and spine (only during open surgery in spine). These defects may be surgically created osseous defects or osseous defects from traumatic injury to the bone.

CERAMENT™|BONE VOID FILLER provides a bone void filler that resorbs and is replaced by bone during the healing process.

Pre-clinical Testing

Extensive in vitro and in vivo testing has shown that the CERAMENT™|BONE VOID FILLER (A0210 –12) meets the requirements of all relevant standards for Calcium Salt Bone Void Fillers .

Summary

Based on the information provided in this premarket notification, the CERAMENT™|BONE VOID FILLER (A 0210-12) is equivalent to the predicate device in intended use, technological characteristics and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

BONESUPPORT AB
% Ms. Ann-Christine Provoost
Regulatory Affairs
Scheelevägen 19A
Ideon Science Park
SE-223 70 LUND, Sweden

SEP - 4 2009

Re: K090871
Trade/Device Name: CERAMENT™| BONE VOID FIILLER (A0210-12)
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: August 24, 2009
Received: August 27, 2009

Dear Ms. Provoost:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Frie MD for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K090871

Device Name: CERAMENT™|BONE VOID FILLER (A0210-12)

Indications for Use:

CERAMENT™|BONE VOID FILLER is a ceramic bone void filler intended only for orthopedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. CERAMENT™|BONE VOID FILLER is indicated to be injected into bony voids or gaps in the skeletal system, i.e. extremities, pelvis and spine (only during open surgery in spine). These defects may be surgically created osseous defects or osseous defects from traumatic injury to the bone.

CERAMENT™|BONE VOID FILLER provides a bone void filler that resorbs and is replaced by bone during the healing process.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K090871